REMARKS

Upon entry of this amendment, Claims 1 – 2, 5 – 15, 17 and 23-27 will be active. Limitations of Claims 2 and 4 have been incorporated into claim 1; Claim 4 having been canceled.

The claims relate to methods of treatment and to compositions for treating skin disorders *consisting of* from about 18 to about 27 percent by weight of beeswax; an oleaginous base of about 5% by weight olive oil, about 21% by weight sunflower oil, about 21% by weight almond oil, about 10% by weight cod liver oil, about 3% by weight castor oil; an added vitamin selected from the group consisting of vitamin A, D and E; a pharmaceutically acceptable excipient and a preservative.

The applicants have found that this particular combination is superior for treating burns and promoting healing compared to a combination of beeswax and oil, such as disclosed by the Soto reference. A human clinical trial is described in the Omonge Declaration, submitted herewith pursuant to 37 CFR 1.132.

In addition, the claimed composition has a surprisingly non-greasy feel and performs better than is a standard drug preparation for treatment of burns containing silver sulfadiazine (SSD). To briefly review, the Tabuke Declaration submitted December 2, 2002, showed that superficial burn patients took 11.3 days on average to heal using the SENCIL® preparation versus 15.8 days on average using SSD. Pain control was also better with the SENCIL® because 55 individuals or 88% of the burn patients experienced no pain on SENCIL® as opposed to only 50 individuals or 75% of the burn patients on SSD.

Claims 1, 2, 4-15, 17 and 24-27 are rejected under 35 USC 103(a) over George, in view of Soto, Ahrens, Kaplan and Slimak.

George discloses a medicinal preparation for skin containing a combination of cod liver oil and castor oil only. The fish oil is said to be a vehicle for the castor oil (Column 2, lines 24-26). The castor oil prevents the growth of scar tissue, and the fish oil controls the caustic action of the castor oil, while at the same time promoting the healing of the wound. (Column 2, lines 43-48). In contrast the components of the present invention corresponding to a "vehicle" are beeswax and an excipient like petroleum jelly. One would not be motivated to modify the

composition of George by adding beeswax (or any of the other oils recited in the claims, i.e., olive oil, sunflower oil and almond oil in *specific* amounts) since cod liver oil is already serving the vehicle function.

Soto is cited for teaching the use of olive oil and beeswax to treat skin injuries. Slimak also teaches a composition comprising oil and beeswax for the treatment of skin.

Sencil ointment is representative of the present invention. The applicant has compared the efficacy of Sencil ointment and "Ointment B," which contains olive oil and beeswax in approximately equal proportions, in clinical trials to evaluate it effect on four skin conditions: itching, dryness, rash, and pain, in 60 patients. The results are summarized in Table 4 of the Omonge Declaration (submitted herewith unexecuted) and reproduced below for confidence.

Table 4.

OUTCOME MEASURES-day symptoms cleared

		DAY 1	DAY 2	DAY 3	DAY 4	DAY 5	Total
Symptom							
Itching	Sencil	2	4	1	1	0	8
	Ointment B	0	0	1	0	8	9
Dryness	Sencil	3	5	2	0	0	10
	Ointment B	0	0	1	3	4	8
Rash	Sencil	1	2	3	1	0	7
	Ointment B	0	0	1	3	4	7
Pain	Sencil	1	3	1	0	0	5
	Ointment B	0	0	1	2	3	6
							60

One can see that the onset of relief occurred more quickly using Sensil in each trial.

As the examiner has stated, neither George or the combination of Slimak, Soto and Kaplan teach compositions containing all of the claimed components. A person of skill in the art would not have been motivated to use all the claimed ingredients *in the recited concentrations*. at least because some are mentioned in the prior art as having the same functions (cod liver oil and petroleum are described as carriers) and there is nothing in the references to guide the selection of the claimed concentrations: one could not have predicted anything from the references about

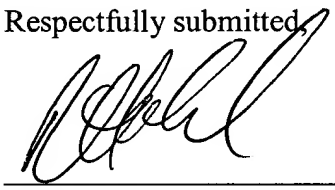
the excellent clinical results obtained by Dr. Omonge Dr. and by Tabuke, and the non-greasy feeling of the claimed mixture.

Accordingly, the claimed mixture consisting of five specific oils and beeswax in recited amounts would not have been obvious within the meaning of 35 USC 103(a).

AUTHORIZATION

Applicants believe there is no additional fee due in connection with this filing. However, to the extent required, the Commissioner is hereby authorized to charge any fees due in connection with this filing to Deposit Account 50-1710 or credit any overpayment to same.

Respectfully submitted,



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Dated: September 15, 2005

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ATTY. DKT. NO. 320607.00100
CUSTOMER NO. 27160 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: R. Vasquez Lipi Examiner: Yu, Gina C.

Serial No.: 09/810,660

Art Unit:

Filed: March 19, 2001 1617

For: TOPICAL MEDICAMENT FOR SKIN INJURIES AND DISORDERS

DECLARATION UNDER 37 C.F.R. §1.132

Commissioner for Patents

Washington, DC 20231

Sir:

I, Dr. O. Omonge *MBcHB, MMED*, do hereby make the following declaration:

1. I am currently on staff at Kenyatta National Hospital, Nairobi, Kenya.

2. The following experiments were carried out by me or under my direct supervision and control.

3. A COMPARATIVE STUDY OF EFFICACY BETWEEN SENCIL® OINTMENT AND OINTMENT B

Summary

We evaluated and compared the efficacy of Sencil ointment and Ointment B in the relief of minor skin lesions in 60 patients of whom 36 were female and 24 were male. The mean age of the patients was 28.5 years.

Sencil ointment contains cod liver and petrolatum as the active ingredient and a mixture of the following olive oil, almond oil, castor oil, sunflower oil, and beeswax. Ointment B contains olive oil and beeswax in approximately equal proportions.

4. *Introduction*

The skin is the largest organ on the body, and is made up of several different components, including water, protein, lipids and different minerals and chemicals. On average the skin weighs about six pounds. The main function of the skin is protection from infections and germs. The skin regenerates approximately every twenty seven (27) days. Proper skin care is essential to maintaining the health and vitality of this protective organ.

Minor skin lesions are a common occurrence in any clinical set up. The lesions we evaluated included sunburn, dermatitis, insect bites, burns and abrasions. The aim of the present study was to compare the efficacy of these two ointments in the management of the above minor skin lesions.

5. *Materials and Methods*

The study was carried out between February and March 2005 at the dermatology outpatient clinic of Kenyatta National Hospital, Nairobi, Kenya. The study consisted of 60 participants, 36 females and 24 males with various minor skin ailments. The participants were randomly assigned to either one of the two ointments. Prior to recruitment all patients gave an informed consent, for those below 18 years a legal guardian who happened to be the parents in all seven cases gave the consent. The patients were given appropriate instructions on how to apply the ointment. They were to apply the ointment twice a day after ensuring that the area was clean. The patient was examined and sent to the laboratory for basic blood works, which included a full blood count, and a urinalysis. Follow up and review was done on day 5, a follow up exam was done and the patient reported on what day the symptoms disappeared and the results were recorded. No further follow up was deemed necessary.

6. *Results*

The primary outcome measure was resolution of the presenting symptom; this was assessed subjectively by asking the patient how they felt and objectively by examining the patient on day 5, after treatment. The patient would then report when the symptoms disappeared and this would be recorded on the patients' card. Analysis was done using Chi-square and F-test a form of ANOVA for computation of variance between two variables. The patients in the two treatment arms were similar in terms of age and sex, as seen from the p-value=0.000, and therefore comparability was justified. See table 1 below.

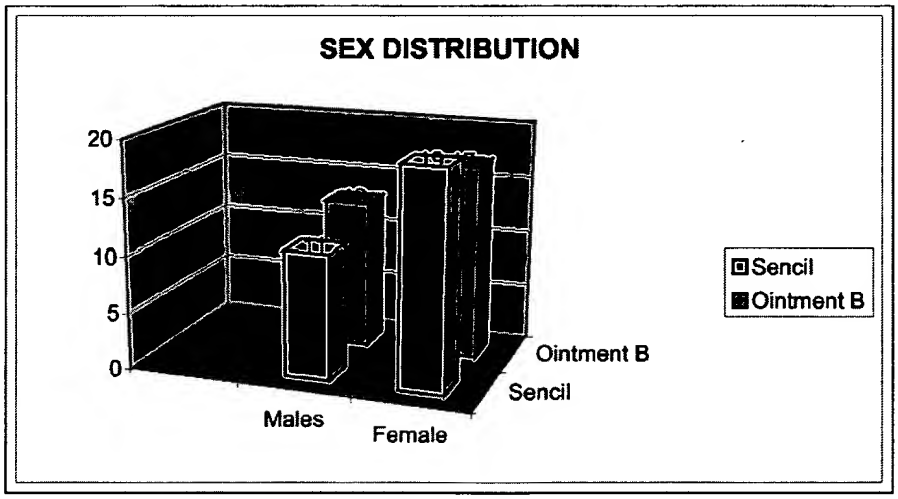
Table 1.

Age and sex distribution of 60 patients with skin lesions

Age range (yrs)	Male	Female	Total no of patients
>25	6	12	18
25-35	5	6	11
35-40	5	8	13
40-45	4	6	10
>45	4	4	8
Total	24	36	60

p-value=0.000 < 0.05. Statistically insignificant. The two treatment arms are similar.

Figure 1.



The results show that there is no difference between sex distribution in the two treatment arms p-value= 0.000. The two groups are comparable.

Table 2.

Presenting symptoms in order of frequency in 60 patients with skin lesions

Symptom	Sencil	Ointment B	Total
Itching	8	9	17
Dryness	10	8	18
Rash	7	7	14
Pain	5	6	11
Total	30	30	60

Table 3.

Skin Lesions seen in patients in KNH
Total number of cases = 60

Type of lesion	Sencil	Ointment B	Total
Dermatitis	7	9	16
Sunburn	7	5	12
Burn	5	5	10
Abrasion	6	7	13
Insect bite	5	4	9
Total	30	30	60

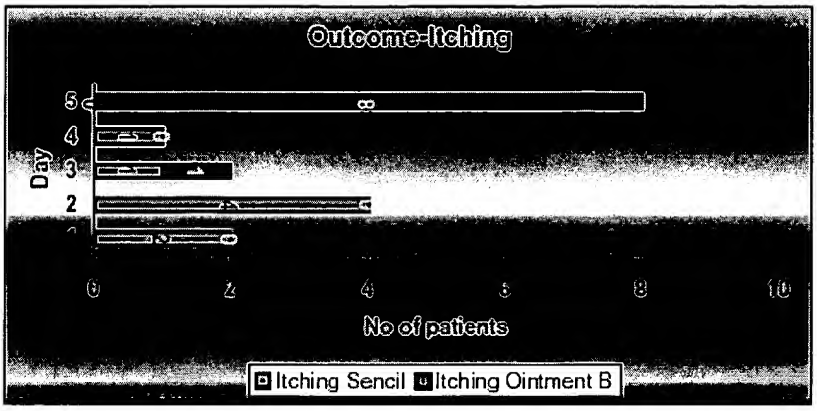
Table 4.

OUTCOME MEASURES-day symptoms cleared

		DAY 1	DAY 2	DAY 3	DAY 4	DAY 5	Total
Symptom							
Itching	Sencil	2	4	1	1	0	8
	Ointment B	0	0	1	0	8	9
Dryness	Sencil	3	5	2	0	0	10
	Ointment B	0	0	1	3	4	8
Rash	Sencil	1	2	3	1	0	7
	Ointment B	0	0	1	3	4	7
Pain	Sencil	1	3	1	0	0	5
	Ointment B	0	0	1	2	3	6
							60

Figure 2.

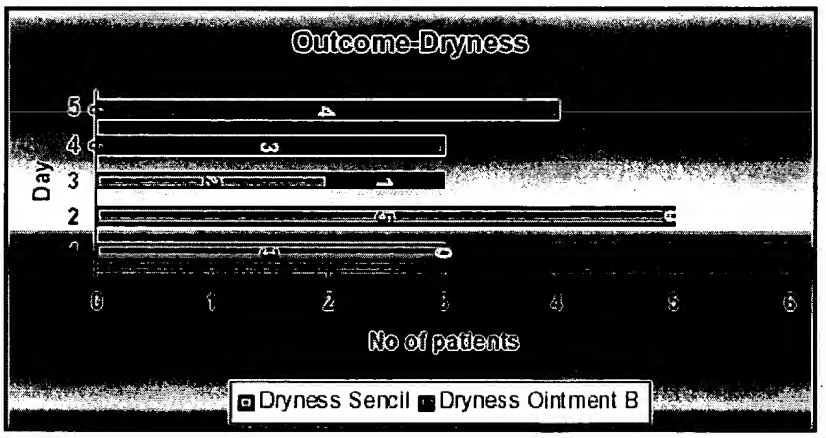
Resolution of itching



p-value= 0.0675 Statistically significant- there is a difference between the two treatments.

On the first day after starting treatment, two patients on Sencil reported relief in itching, while none on ointment B reported any relief.
On the second day after starting treatment four patients on Sencil reported relief in itching, while none on ointment B reported any relief.
On the third day after starting treatment, one patient on Sencil and one patient on ointment B reported relief in itching.
On the fourth day after starting treatment, one patient on Sencil reported relief in itching while none on ointment B reported any relief.
On the fifth day after starting treatment the remaining eight patients on Ointment B reported some relief in itching.

Figure 3.



Resolution of dryness

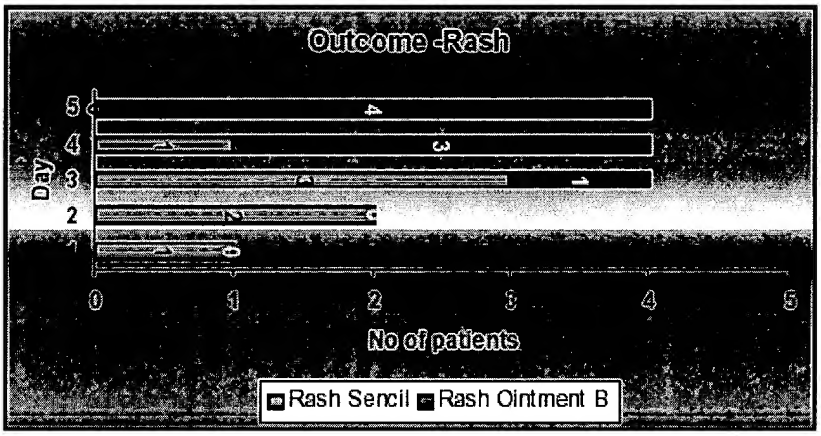
p-value= 0.0471 Statistically significant-there is a difference between treatments.

On the first day after starting treatment, three patients on Sencil reported relief in dryness, while none on ointment B reported any relief.

On the second day after starting treatment five patients on Sencil reported relief in dryness, while none on ointment B reported any relief.
On the third day after starting treatment, two patients on Sencil and one patient on ointment B reported relief in dryness.
By the third day all the patients on Sencil had experienced relief in their symptoms.
On the fourth day after starting treatment, three patients on ointment B reported relief in dryness.
On the fifth day after starting treatment the remaining four patients on Ointment B reported some relief in dryness.

Figure 4.

Resolution of rash

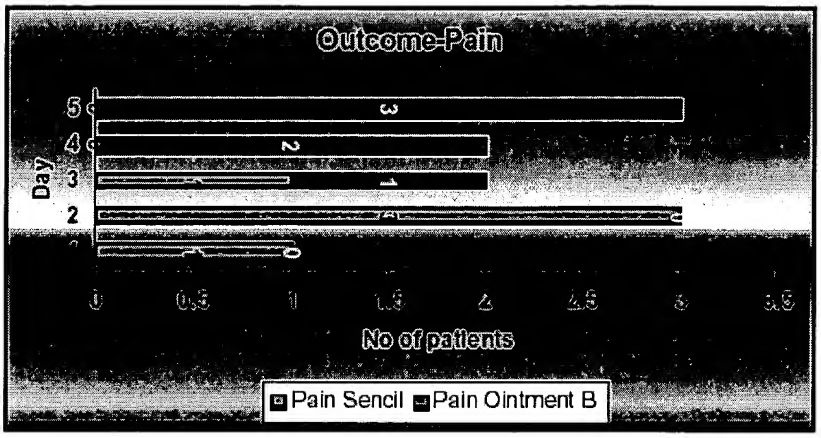


p-value = 0.0424 Statistically significant-there a difference between the treatments.

On the first day after starting treatment, one patient on Sencil reported resolution of the rash, while none on ointment B reported any relief.
On the second day after starting treatment two patients on Sencil reported resolution of rash, while none on ointment B reported any relief.
On the third day after starting treatment, three patients on Sencil and one patient on ointment B reported resolution of the rash.
On the fourth day after starting treatment, one patient on Sencil and three on ointment B reported resolution of the rash.
On the fifth day after starting treatment the remaining four patients on Ointment B reported some relief in the rash.

Figure 5.

Relief of pain



p-value = 0.4692 Statistically insignificant-there is **NO** difference between treatments.

On the first day after starting treatment, one patient on Sencil reported relief in pain, while none on ointment B reported any relief.
On the second day after starting treatment three patients on Sencil reported relief in pain, while none on ointment B reported any relief.
On the third day after starting treatment, one patient on Sencil and one patient on ointment B reported relief in pain
By the third day all the patients on Sencil reported relief.
On the fourth day after starting treatment two patients on ointment B reported relief in pain.
On the fifth day after starting treatment the remaining three patients on Ointment B reported relief in pain.

7. The purpose of this study was to compare and evaluate the effects of Sencil ointment and Ointment B. Based on the findings of this study, the results demonstrate that Sencil ointment was overall superior to Ointment B. The above results indicate that there was both a statistical and a clinical difference between the treatment arms for itching, dryness and rash. Sencil showed superior outcomes in all three cases. However, in the case of pain the two ointments were the same; none was superior to the other.

8. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Dated: _____ By: _____

Dr. O. Omonge *MBcHB, MMED*